(*http://www.fda.gov/cdrh/ombudsman/dispute.html*).

[67 FR 38887, June 6, 2002, as amended at 72 FR 17399, Apr. 9, 2007]

Subpart C—Postmarket Surveillance Plan

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Postmarket Surveillance Document Center (HFZ–541), Epidemiology Branch, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

[67 FR 38887, June 6, 2002, as amended at 70 FR 14986, Mar. 24, 2005; 73 FR 49942, Aug. 25, 2008]

§ 822.9 What must I include in my submission?

Your submission must include the following:

(a) Organizational/administrative information:

(1) Your name and address;

(2) Generic and trade names of your device;

(3) Name and address of the contact person for the submission;

(4) Premarket application/submission numbers for your device;

(5) Table of contents identifying the page numbers for each section of the submission;

(6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);

(7) Product codes and a list of all relevant model numbers; and

(8) Indications for use and claims for the device;

(b) Postmarket surveillance plan;

(c) Designated person information;

(1) Name, address, and telephone number; and

(2) Experience and qualifications.

§ 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:

(a) The plan objective(s) addressing the surveillance question(s) identified in our order;

(b) The subject of the study, e.g., patients, the device, animals;

(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;

(d) The surveillance approach or methodology to be used;

(e) Sample size and units of observation;

(f) The investigator agreement, if applicable;

(g) Sources of data, e.g., hospital records;

(h) The data collection plan and forms;

(i) The consent document, if applicable;

(j) Institutional Review Board information, if applicable;

(k) The patient followup plan, if applicable;

(l) The procedures for monitoring conduct and progress of the surveillance;

(m) An estimate of the duration of surveillance;

(n) All data analyses and statistical tests planned;

(o) The content and timing of reports.